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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

PRELIMINARY

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/029,872

Applicant(s)
Pugh et al

Examiner
Paul Prebilio

Art Unit
3738



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 4, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 10, 12-15, 19-35, 37, and 38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 20, and 37 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 12-15, 19, 21-35, and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 3738

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2001 (the copy of the amendment filed May 29, 2001) has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, line 4, "tricalcium" should be ---calcium--- in order to have proper antecedent basis and in order to be consistent with what was earlier set forth in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 12-15, 21-35 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

Art Unit: 3738

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The language “substantially uniformly stabilized calcium phosphate” and “distributed substantially uniformly throughout” lacks original support because “substantially” was not defined as to how limiting it is. Applicant did not originally contemplate a partially stabilized and a substantially uniform distribution of stabilizing entities as part of the originally disclosed invention.

The claims also now have terminology which is not adequately described in the specification. Particularly, “substantially” is a broad term; see MPEP 2173.05(b)(D) and *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) which are incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know what degree of stabilization or uniform distribution would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes

Art Unit: 3738

substantially stabilized and substantially uniformly distributed and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 6, 12-15, 21-35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the limitations of "substantially stabilized" and "substantially uniformly distributed" were not clearly defined, their scope is considered indefinite such that the claims are rendered indefinite; see the Section 112, first paragraph rejection pertaining to this issue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3738

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 6, 12-15, 21-35, and 38 are rejected under 35 U.S.C. 102(a) or 102(b)* as being anticipated by Davies (WO 94/26872), or alternatively, under 35 U.S.C. 103(a) by Davies (WO 94/26872) alone. Davies discloses a sintered hydroxyapatite and tricalcium phosphate film on quartz (see pages 26-28). This procedure is identical to the present specification's manner of stabilizing hydroxyapatite due to the silica of quartz permeating into the sol during sintering; see Procedure 3 on page 30 of the present specification and note that only the bulk ceramic pieces need to be doped with a stabilizer because the quartz substrate inherently dopes the sol-gel. The Examiner posits that the stabilization of hydroxyapatite is not mentioned by Davies, nonetheless, this property is inherently present because it is made the same way as in the present specification; see also pages 6, 7, and 15 of Davies. Moreover, the distribution of the silicon entities is considered to be "substantially" uniform because of the broad nature of this term as explained in the Section 112 rejections earlier. In particular, the language does not preclude the presence of a gradient as long as it is not too pronounced. In addition, since the Davies layer is rather thin, it would have silicon diffused throughout.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was

Art Unit: 3738

broadened from the meaning it had in the parent application filed before August 30, 1996. Alternatively, if the earlier date for the claims has support, the Davies constitutes a 35 USC 102(a) reference. Moreover, it is posited that claim 38 has the August 30, 1996 effective filing date because it does not preclude other entities and can encompass a plurality of later added stabilization entities.

Alternatively, one could view the Davies et al disclosure as not fully meeting the claim language because it does not explicitly teach uniform distribution. However, the Examiner posits that the substantially uniform distribution of stabilizing entities is at least obviated by Davies because of the diffusion of the entities into the surface.

With regard to claims 24-26 and 32, Davies anticipated the claim language wherein the Examiner posits that the same structure must exist therein due to the fact that it is made in the same manner as the disclosed and claimed invention of the present claims. Davies even discloses that the material can be porous; see page 21. Alternatively, the Examiner posits that the claimed product is at least substantially identical to that disclosed by Davies such that the claimed invention is clearly obvious; see MPEP 2113 which is incorporated into this Office action by reference.

With regard to claims 27-29, the Examiner posits that the claimed matrix would inherently be present in the Davies device due to the same device being exposed to the same cells for a sufficient time for such matrix to form. Alternatively, the Examiner posit that the claimed matrix is at least obvious in view of Davies alone due to its clearly similar method of making.

Art Unit: 3738

Claims 1-3, 12-14, 19, 22, 23, 31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al (US 5,232,878) wherein the stabilizing entities are the alkaline earth metal silicates of the second step where hydroxyapatite is used. Also, zirconia and alumina may serve as stabilization entities in the fourth step; see the whole document, especially the abstract, Col. 1, lines 5-10; Col. 3, lines 3-37; Col. 5, line 9 to Col. 6, line 24; Col. 6, lines 64-67 and Col. 8, lines 56-61.

Claims 1-3, 5, 6, 12-14, 21, 23, 24, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kijima et al (US 4,983,182) wherein zirconia is used to stabilize hydroxyapatite to the extent required by the present claims; see the whole document.

Allowable Subject Matter

Claim 10, 20, and 37 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments filed September 4, 2001 have been fully considered but they are not persuasive.

Applicant traverses the Davies et al rejections by asserting that the silicon stabilizing entities are not substantially uniformly distributed as now claimed. However, this issue has been addressed in the Section 112 and Section 102 rejections utilizing Davies et al.

In response to the argument that Kasuga et al and Kijima et al not directed to bioactive compositions of claims 1, 13, and 19, the Examiner notes that the claims do not include any such

Art Unit: 3738

limitation. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Even if the limitation were claimed, the Examiner would apply a teaching secondary reference which shows that it was known to use bioactive compound in similar bone compositions.

In response to the traversal that Kijima et al does not teach uniform distribution, it is the Examiner's position that zirconia, which is disclosed as a stabilizing entity on pages 15-16 of the present specification, is uniformly distributed throughout the coating layer. Since the coating layer is a composition, the claims are fully met in this regard. Similarly, Kasuga et al teaches the use of zirconia and/or alumina, which are both disclosed in Applicant's specification as stabilization entities, throughout an sintered inorganic biomaterial. For this reason, the claims are fully met.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nonami (JP 401298055A) is cited to show that boron stabilized calcium phosphate artificial bone materials were known at the time the present invention was made. Nijhawan et al teaches that a sintered mixture of calcium phosphate and calcium oxide were known at the time the inventions were made.

Art Unit: 3738


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
Art Unit 3738